

CLAIMS

- sub a1
1. A pharmaceutical composition in the form of tablets or capsules which constitutes an oral controlled drug delivery system, comprising a drug, a gas generating component, a swelling agent, a viscolyzing agent, and optionally a gel forming polymer, said pharmaceutical composition providing a combination of temporal and spatial control of drug delivery when ingested by a patient.
2. The pharmaceutical composition of claim 1 wherein the drug is selected from the group consisting of therapeutic, chemotherapeutic, antibiotic, anti-cancer, anti-fungal, anti-filarial, anti-ulcer, anti-viral, anti-gout, cardiovascular, anti-inflammatory, respiratory, immunosuppressant and lipid lowering drugs.
3. The pharmaceutical composition of claim 1 wherein the drug is selected from the group consisting of ciprofloxacin, acyclovir, diltiazem, ranitidine, captopril, and their pharmaceutically acceptable salts and esters.
4. The pharmaceutical composition of claim 1 wherein the drug is present in an amount ranging from about 0.5 mg to 1200 mg.
5. The pharmaceutical composition of claim 1 wherein the gas generating component is a sulfite, a carbonate or a bicarbonate salt.

6. The pharmaceutical composition of claim 1 wherein the gas generating component is selected from the group consisting of sodium bicarbonate, potassium bicarbonate, sodium glycine carbonate, calcium carbonate, sodium sulfite, sodium bisulfite, and sodium metabisulfite.

5

7. The pharmaceutical composition of claim 1 wherein the gas generating component is a gas couple comprising a gas generating salt and an edible organic acid or a salt of an edible organic acid. *1/2 ?*

10 8. The pharmaceutical composition of claim 7 wherein the edible organic acid is selected from the group consisting of citric acid, ascorbic acid, tartaric acid, succinic acid, fumaric acid, malic acid, maleic acid, glycine, sarcosine, alanine, taurine, and glutamic acid.

9. The pharmaceutical composition of claim 1 wherein the gas generating component comprises about 5% to about 50% by weight of said composition.

10. The pharmaceutical composition of claim 1 wherein the gas generating component comprises about 10% to about 30% by weight of said composition.

20 11. The pharmaceutical composition of claim 1 wherein the swelling agent comprises a superdisintegrant.

12. The pharmaceutical composition of claim 1 wherein the swelling agent is selected from the group consisting of cross-linked polyvinylpyrrolidone, cross-linked sodium carboxymethylcellulose, and sodium starch glycolate.

13. The pharmaceutical composition of claim 1 wherein the swelling agent comprises about 5% to about 50% by weight of said composition.

14. The pharmaceutical composition of claim 1 wherein the swelling agent comprises about 10% to about 30% by weight of said composition.

15. The pharmaceutical composition of claim 1 wherein the swelling agent comprises about 10% to about 20% by weight of said composition.

16. The pharmaceutical composition of claim 1 wherein the viscolyzing agent comprises a carbohydrate gum.

17. The pharmaceutical composition of claim 1 wherein the viscolyzing agent is selected from the group consisting of xanthan gum, tragacanth gum, gum karaya, guar gum, and acacia

18. The pharmaceutical composition of claim 1 wherein the viscolyzing agent comprises about 0.1% to about 30% by weight of said composition.

19. The pharmaceutical composition of claim 1 wherein the viscolyzing agent comprises about 0.1% to about 10% by weight of said composition.

20. The pharmaceutical composition of claim 1 wherein the viscolyzing agent comprises about 0.1% to about 7% by weight of said composition.

21. The pharmaceutical composition of claim 1 wherein the gel forming polymer comprises a water soluble salt of at least one polyuronic acid.

22. The pharmaceutical composition of claim 1 wherein the gel forming polymer comprises an alkali metal salt of alginic acid or pectic acid.

23. The pharmaceutical composition of claim 1 wherein the gel forming polymer is selected from the group consisting of sodium alginate, potassium alginate, ammonium alginate, and mixtures thereof.

24. The pharmaceutical composition of claim 1 wherein the gel forming polymer comprises about 0.1% to about 20% by weight of said composition.

25. The pharmaceutical composition of claim 1 wherein the gel forming polymer comprises about 0.1% to about 10% by weight of said composition.

26. The pharmaceutical composition of claim 1 wherein the gel forming polymer comprises about 0.5% to about 5% by weight of said composition.
27. The pharmaceutical composition of claim 1 further comprising an additional hydrophilic water soluble polymer.
28. The pharmaceutical composition of claim 27 wherein the additional hydrophilic water soluble polymer is hydroxypropyl methylcellulose, hydroxypropylcellulose, polyacrylic acid, or mixtures thereof.
29. The pharmaceutical composition of claim 27 wherein the additional hydrophilic water soluble polymer comprises about 0.5% to about 20% by weight of said composition.
30. The pharmaceutical composition of claim 27 wherein the additional hydrophilic water soluble polymer comprises about 0.5% to about 10% by weight of said composition.
31. The pharmaceutical composition of claim 27 wherein the additional hydrophilic water soluble polymer comprises about 0.5% to about 5% by weight of said composition.
32. The pharmaceutical composition of claim 1 in the form of a tablet which is coated with a rapidly dissolving water soluble film forming polymer or a rapidly dissolving pharmaceutical excipient.

33. A pharmaceutical composition in the form of tablets or capsules for the controlled delivery of a drug, comprising the drug in an amount suitable for sustained release to a patient, about 5 to about 50% by weight of a gas generating component, about 5 to about 50% by weight of a swelling agent, about 0.1% to about 30% by weight of a viscolyzing agent, and optionally about 0.1% to about 20% by weight of a gel forming polymer.

34. The pharmaceutical composition of claim 33 wherein the drug is selected from the group consisting of ciprofloxacin, acyclovir, diltiazem, ranitidine, captopril, and their pharmaceutically acceptable salts and esters.

35. The pharmaceutical composition of claim 33 wherein the drug is present in an amount ranging from about 0.5 mg to 1200 mg.

36. The pharmaceutical composition of claim 33 wherein the gas generating component is a sulfite, a carbonate or a bicarbonate salt.

37. The pharmaceutical composition of claim 33 wherein the gas generating component is selected from the group consisting of sodium bicarbonate, potassium bicarbonate, calcium carbonate, sodium sulfite, sodium bisulfite, sodium metabisulfite, and sodium glycine carbonate.

38. The pharmaceutical composition of claim 33 wherein the gas generating component includes an acid source which comprises about 0.5% to about 15% by weight of said composition.

5 39. The pharmaceutical composition of claim 38 wherein said acid source comprises an edible organic acid, a salt of an edible organic acid, or mixtures thereof.

40. The pharmaceutical composition of claim 33 wherein the swelling agent is selected from the group consisting of cross-linked polyvinylpyrrolidone, cross-linked carboxy-
10 methylcellulose sodium, and sodium starch glycolate.

41. The pharmaceutical composition of claim 33 wherein the viscolyzing agent, is selected from the group consisting of xanthan gum, tragacanth gum, gum karaya, guar gum, and acacia.

15 42. The pharmaceutical composition of claim 33 wherein the gel forming polymer is a water soluble salt of one or more polyuronic acids.

43. The pharmaceutical composition of claim 33 wherein the gel forming polymer is
20 sodium alginate.

44. The pharmaceutical composition of claim 33 further comprising about 0.5% to about 20% by weight of an additional hydrophilic water soluble polymer.

45. The pharmaceutical composition of claim 44 wherein the additional hydrophilic water soluble polymer is selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropylcellulose, polyacrylic acid, and mixtures thereof.

46. The pharmaceutical composition of claim 33 in the form of a tablet which is coated with a rapidly dissolving water soluble film forming polymer or a rapidly dissolving pharmaceutical excipient.

47. A once daily formulation for the controlled release of ciprofloxacin comprising a pharmaceutically effective amount of ciprofloxacin, about 0.2% to about 0.5% sodium alginate, about 1.0 to about 2.0% xanthan gum, about 10.0% to about 25% sodium bicarbonate, and about 5.0% to about 20% cross-linked polyvinylpyrrolidone, said percentages being w/w of the composition, wherein the weight ratio of sodium alginate to xanthan gum is between about 1:1 to about 1:10.

48. The formulation of claim 47 comprising 69.9% ciprofloxacin base, 0.34% sodium alginate, 1.03% xanthan gum, 13.7% sodium bicarbonate, 12.1% cross-linked polyvinylpyrrolidone, and optionally other pharmaceutical excipients.

49. The formulation of claim 47 in the form of a tablet or a capsul .

50. The formulation of claim 47 which is coated with a pharmaceutically acceptable film forming polymer or a pharmaceutical excipient.